PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
NO 7274/WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/013787	03.12.2004	20.12.2003

International Patent Classification (IPC) or national classification and IPC

A23L1/305, A23L1/29, A61K31/401

Applicant

NESTEC S.A. et al

1. This report is the International preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *sent to the applicant and to the International Bureau)* a total of sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the opinion
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
08.07.2005	01.02.2006
Name and mailing address of the international preliminary examining authority:	Authorized Officer
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/013787

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-8 as originally filed

   Claims, Numbers

   1-11 as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 6-8

because:

☒ the said international application, or the said claims Nos. 6-8 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-11
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-11
Industrial applicability (IA)	Yes:	Claims	1-5,9-11
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

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ITEM III

Claims 6-8 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

For the assessment of the present claims 6-8 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment. The search has been carried out on the alleged effects of the composition and these effects will also be discussed below.

ITEM V

1. The following documents (D) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: US-A-5 384 308 (HENKIN R I) 24 January 1995 (1995-01-24)
D2: DE 102 21 403 A (KYBERG PHARMA VERTRIEBS GMBH &) 4 December 2003 (2003-12-04)
D3: EP-A-0 764 405 (CLINTEC NUTRITION CO) 26 March 1997 (1997-03-26)
D4: WO 01/78532 A (NESTLE SA ;BOZA JULIO (CH); BALLEVRE OLIVIER (CH); FINOT PAUL ANDR) 25 October 2001 (2001-10-25)
D5: WO 03/075903 A (UNIVERSITEIT LEIDEN ;MATYSIK JOERG (NL); ALIA (NL); BACKENDORF CLA) 18 September 2003 (2003-09-18)
D6: EP-A-1 161 945 (SOLARTIUM ESTABLISHMENT) 12 December 2001 (2001-12-12)
D7: WO 03/013487 A (DIOGUARDI FRANCESCO SAVERIO ;CONTI FRANCO (IT); PROFESSIONAL DIETE) 20 February 2003 (2003-02-20)

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2. NOVELTY OBJECTIONS

D1 describes a composition for promoting wound healing comprising a protein, lipid and carbohydrate source (claims 1,2, table 1). The protein source contains proline 32.7 % and arginine 3.7 % (table 1). The protein is diluted while making an emulsion in a way (column 8 lines 9-18), that the final emulsion contains proline at least 3 % and arginine no more than 1.8 % of the total calories. Consequently, the subject matter of claims 1-11 is considered as being not new in view of D1 (Art 33 (2) PCT).

3. INVENTIVE STEP OBJECTIONS

D2 describes a nutritional composition containing amino acid mixture (proline more than 3 % and arginine less than 1.8 %) with proteins, lipids and carbohydrates. Use for wound healing mentioned (claims 1,2,12,13,22). There is no clear example containing all these features together, but a skilled person would consider combining proline (well known to be used in wound healing to synthesize collagen) rich composition for wound healing. Consequently, the subject matter of claim 1-11 is considered as being not inventive in view of D2 (Art 33 (3) PCT).

D3 describes a composition for promoting wound healing and nutrient absorption comprising a protein, lipid and carbohydrate source. The protein source contains proline and arginine for wound healing (example 2, page 2 line 26-31, 53,54, page 3 lines 36-41).

D4 describes a composition for promoting wound healing comprising a protein, lipid and carbohydrate source. The protein source contains proline for wound healing (5-6 %) and amount of arginine that is supposed to be lower than usual (2.3-7 %) when used for wound healing (claims 2,4,9,16, page 4 lines 1-9,30-32, page 5 line 28- page 7 line 17).

D5 describes the use of protein containing high amount of proline (up to 40 %) in wound healing (inflammation) in food and pharmaceuticals (claims 1,2,6-9,22,30, page 3 line 10-20, page 8 line 7-20).

D6 describes the use of amino acid mixture containing high amount of proline (10-50 %) in wound healing in pharmaceuticals (claims 1,6, page 2 lines 5-8,21-24, page 3 lines 15-31).

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D7 describes the use of amino acid mixture containing high amount of proline (7-40 %) in wound healing in pharmaceuticals (claims 1,7 page 3 lines 2-12, page 4 lines 18-35).

The difference between D3, D4 and this application is, that D3, D4 do not contain correct amount of proline and arginine. D5-D7 describe products having high level of proline and hardly any arginine used in wound healing. Since both D3,D4 and the application are solving the same problem (wound healing by synthesizing collagen), a skilled person would consider using a composition of having high level of proline and low level arginine because knowing D5-D7. Consequently, the subject matter of claims 1-11 is considered as being not inventive in view of D3-D7 (Art 33 (3) PCT).

None of the claimed compositions with uses are considered to be inventive in view of D1-D7 (Art 33(3) PCT). Having regard to the claimed compositions with uses and the prior art known (D1-D7), it is considered that the man skilled in the art would regard these compositions, uses or methods of the present invention (as far as novel) as an obvious alternative to those known. Therefore, unless an unexpected effect for the present compositions with uses (as far as novel) over the prior art disclosure from D1-D7 can be demonstrated, these compositions with uses do not fulfill the requirements of Art 33(3) PCT.